No. 95-35 (4)

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

ORTHO PHARMACEUTCAL CORP.,

Petitioner,

—v.—

GENETICS INSTITUTE, INC. and AMGEN, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITIONER'S REPLY

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On A Petition For A Writ of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITIONER'S REPLY BRIEF

Reply Argument

Respondents cannot reconcile *Independent Wireless*[1] and the decision below. Their basic argument -- that *Independent Wireless* retains continued vitality because the Federal Circuit purported to apply it -- misses the point entirely. It glosses over the important issues that are presented for this Court's review.

This Court should grant certiorari *not* because the decision below overlooks *Independent Wireless* -- it doesn't -- but rather because it eviscerates *Independent Wireless* in the

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1 *Independent Wireless Telegraph Co. v. Radio Corp. of America*, 269 U.S. 459 (1926).

guise of applying it. It does so by requiring, as a condition for licensee standing, that the license be exclusive not only in the *relevant field-of-use*, but also in the *totality* of the "use" right. Because field-of-use licenses, by definition, *never* confer exclusive rights in the *totality* of the "use" right, this is a test for standing that field-of-use licensees can never meet.

1. Respondents Cannot Identify Anything "Nonexclusive" About Ortho's Rights In The Relevant Field-Of-Use

Respondents describe the decision below as applying *Independent Wireless*. But they are unable to find anything in that decision, or in the License Agreement, that could support the characterization of Ortho's rights as non-exclusive *in the relevant field-of-use*. Like the court below, they characterize Ortho's rights as non-exclusive only by looking *outside* the relevant field-of-use.

For example, Amgen contends that Ortho's rights are non-exclusive because it, Amgen, supposedly retained the right to use the patented invention and to grant additional sublicenses for its use. Amgen Brief at 10-11. Although Amgen reserved such rights *outside* the relevant field-of-use, it did not do so within that field.

The district court's findings on this point are clear. The district court found that Amgen reserved certain rights *outside* Ortho's field-of-use, including the right to: (a) use the patented inventions to make EPO for sale "*in the U.S.* for *dialysis and diagnostic purposes*," App. B at B-16-17 (emphasis in original), and (b) to "grant additional licenses to use the patented '008 inventions in the U.S. to make EPO for use or sale *in the U.S.* for *dialysis and diagnostic purposes*." *Id.* (emphasis in original).

Significantly, the district court found no similar reservation of rights by Amgen *within* the relevant field-of-use. In fact, the district court found precisely the opposite. The district court repeatedly described Ortho's rights within the relevant field as "exclusive." *See, e.g.*, App. B at B-17. Moreover, it found that paragraph 2.01(b) of the License Agreement (which defines Ortho's exclusive field-of-use) "clearly . . . precludes Amgen from licensing to any third parties the right to [use the patented invention] to manufacture EPO . . . for sale abroad." *Id.* On appeal, Amgen did not challenge these findings, and the court of appeals did not disturb them.

These fact findings are plainly correct. The License Agreement is "straightforward" (Amgen Brief at 1), and it does not contain any reference to the rights that Amgen now says it reserved in the relevant field-of-use.

Respondents place great emphasis on a statement from the court of appeals' decision, to the effect that Amgen retained "the right to license others" to "use the '008 invention in one location in the United States." App. A at A-12. This statement, however, is not specific to the relevant field-of-use. In light of the district court's unchallenged finding that the License Agreement "clearly . . . precludes" Amgen from licensing others to practice the patent in that particular field, App. B. at B-17, the court of appeals' statement can only be understood as referring to a right that Amgen did retain, *i*.e., the right to grant additional licenses *outside* the relevant field.

Like the court below, respondents can describe Ortho's rights as non-exclusive only by focussing on the "use" right as an undifferentiated whole, instead of on the relevant field-of-use. Thus, Amgen argues that Ortho's generalized right "to make EPO in the United States" -- *not* Ortho's right in the specific field-of-use -- is non-exclusive because of "Amgen's

right to do the same."[2] Amgen Brief at 12. Similarly, Genetics Institute offers the conclusory assertion that Ortho's generalized "right to use the '008 invention" is non-exclusive. GI Brief at 11. These arguments miss the point. The basis for Ortho's standing is not a generalized "right to use the '008 invention," or a generalized right "to make EPO." Rather, it is Ortho's exclusive right to use the patented invention in a particular field that is spelled out with specificity in paragraph 2.01(b) of the License Agreement.

Like the court below, respondents incorrectly treat the "use" right under the '008 patent as a generalized, undifferentiated whole, without focusing with the specificity that *Independent Wireless* requires on exclusivity in the relevant field-of-use. That approach cannot be reconciled with *Independent Wireless*.

2. *Respondents' Emphasis On The Right To "Sell" Unpatented EPO Abroad Is A Smokescreen*

Both respondents hide behind a smokescreen. They confuse the right to *sell* unpatented EPO *abroad* (which is not

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2 Even if Amgen had reserved the right to practice the '008 patent in Ortho's field-of-use -- which it clearly did not do -- that would not deprive Ortho of standing to sue Genetics Institute for infringement in Ortho's exclusive licensed field. A patent license must be exclusive as against third-parties but it need not be exclusive *as against the licensor* in order for a licensee to have standing to enforce the patent against third-party infringers. *Western Electric Co. v. Pacent Reproducer Corp.*, 42 F.2d 115, 120 (2d Cir.), *cert. denied*, 282 U.S. 873 (1930); *Research Frontiers, Inc. v. Marks Polarized Corp.*, 290 F. Supp. 725, 727 (E.D.N.Y. 1968).

the basis for Ortho's standing) with the right to *use* the '008 invention *in the United States* for a particular, defined purpose (which *is* the basis for Ortho's standing). Thus, Amgen pretends that Ortho's field-of-use "applies to a territory outside the U.S. . . . for *sale* of the *unpatented* EPO product." Amgen Brief at 11. Similarly, Genetics Institute pretends that Ortho sought standing on the basis of a right to *sell* "unpatented EPO abroad." GI Brief at 11.

Respondents know better. Ortho clearly described the relevant field-of-use in the court below, when it stated:

> The basis for Ortho's standing is an "exclusive" license . . . to *use the '008 inventions* [*i.e.*, the patented DNA sequences and host cells] *in the U.S.* [for a particular purpose, *i.e.*] to make EPO in the U.S. for use and sale outside the U.S.

App. G. at G-4. Ortho's briefs in the court below left no doubt on this point. *See, e.g.*, App. G. at G-1, 6, 13, 17 and 18. Given this emphasis, it is irresponsible for respondents to suggest that the basis for Ortho's standing is a right to *sell* unpatented EPO, abroad or anywhere else.

Unfortunately, respondents are not alone in resorting to this smokescreen; the Federal Circuit made the same error in its decision. App. A at A-14-15.

3. *The Federal Circuit Never Has Recognized Standing For Parties With Exclusive Field-Of-Use Licenses*

Genetics Institute cites *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995), and *Abbott Laboratories*

v. Diamedix Corp., 47 F.3d 1128, 1131 (Fed. Cir. 1995), as evidence that the Federal Circuit follows *Independent Wireless*. *See* GI Brief at 10. Those cases are not on point.

In both cases, the Federal Circuit cited *Independent Wireless* merely for the uncontroversial proposition that "exclusive licensees" have standing to sue for infringement. Neither case addresses the more particularized issue that is presented here, *i.e.*, whether licensees whose rights are exclusive in a *particular field-of-use* also have standing to sue.

The Federal Circuit has not endorsed that principle in any case. The only Federal Circuit case addressing this issue is the decision below.

4. Amgen's ¶ 8.02 Argument Is Specious

In opposing the petition, Amgen advances a theory that neither the district court nor the court of appeals accepted. It argues that the judgment below "may be upheld" on the basis of paragraph 8.02 of the License Agreement, which Amgen reads as giving it alone the right to sue for infringement. *See* Amgen Brief at 15.

Amgen raised the same argument in the district court and in the court of appeals, each time without success. *See* App. A at A-16; App. B. at B-23 at n.16. This alternative argument, already rejected by two lower courts, provides no reason for denying certiorari.

There is a good reason why two lower courts refused to accept Amgen's argument on this point: Contrary to Amgen's contention, paragraph 8.02 expressly recognizes Ortho's right to sue in circumstances like those presented here. Indeed, that paragraph imposes upon Amgen a contractual

obligation to assist Ortho in suing infringers. It requires Amgen to "execute all papers and . . . perform such other acts as may be reasonably required" to assist Ortho in bringing such suits. *See* App. G. at G-18. License terms of this type do "not preclude [an exclusive licensee] from bringing suit" against a third-party infringer. *Brunswick Corp. v. United States*, 22 Cl.Ct. 278, 282 (Ct.Cl. 1991).

5. *Genetics Institute's "Waiver" Theory Does Not Provide A Reason For Denying Certiorari*

Genetics Institute also offers a fallback position. It cites *dicta* in the decision below, which it incorrectly casts as an alternative basis for the lower court's ruling. Relying on this *dicta*, Genetics Institute argues that Ortho "waived" its right to sue for infringement in its exclusive field-of-use. *See* GI Brief at 13. This "waiver" theory is devoid of merit. The undisputed facts, recited below, show that Ortho at all times was vigorous in trying to enforce its rights:

a) Ortho tried to intervene in *Amgen v. Chugai* before trial in the liability phase of that action, only to be denied intervention on the grounds that Amgen could adequately protect Ortho's interests with respect to *liability* (but not with respect to damages). *See* App. C at C-12.

b) Once the liability phase of *Amgen v. Chugai* ended, Ortho promptly brought this action. No defenses based on the statute of limitations or laches were asserted. Nor could these defenses be asserted consistent with Rule 11, Fed.R.Civ.P.

c) Within weeks after it commenced this action,

Ortho sought and obtained an order consolidating this action with the *Amgen v. Chugai* case, so that discovery in the two actions could be coordinated and the cases could be tried together. *See* App. E at E-2.

d) After the district court dismissed this action for lack of standing, Ortho promptly moved for leave to appeal pursuant to Rule 54(b), Fed.R.Civ.P. In response to that motion, the district court entered an order deconsolidating the two cases in order to permit "an expedited appeal" by Ortho. *See* App. F at F-2. Ortho then pursued an appeal in the Federal Circuit.

This undisputed evidence refutes any suggestion that Ortho "waived" its right to recover from Genetics Institute for its infringing acts in Ortho's exclusive licensed field.

6. The Public Importance Of This Case

Respondents do not challenge the public importance of permitting exclusive field-of-use licensees to sue for infringement in the area of an exclusive license, under the standards set forth in *Independent Wireless*. The lower court's departure from those standards -- and its creation of a new test that exclusive field-of-use licensees can never meet -- warrants this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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